

Docket No: ETI-102

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re: Application of: Jugheim et al.

Examiner: Nizal S. Chandrakumar

Application No.: 10/566,012

Confirmation No.: 9306

Filed: January 25, 2006

Art Unit: 1625

For: Compounds, Methods and Formulations For The Oral Delivery of Glucagon Like Peptide (GLP)-1 Compound Or An Melanocortin 4 Receptor (MC4) Agonist Peptide

RESPONSE TO OFFICE ACTION
REQUIRING RESTRICTION / ELECTION OF A SPECIES

Attn.: Office of Petitions
Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Fax 571-273-8300

Dear Sir/ Madam:

This is filed in response to the Office Action mailed on February 6, 2008 concerning the above-referenced patent application, which contained a Restriction Requirement. The term for responding to the Office Action is set to expire on March 7, 2008 which is "30 days...from the mailing date of this communication." Accordingly, this response is timely filed.

The Applicant is a small entity, Emisphere Technologies, Inc.. The Examiner is authorized to charge any fees for a small entity in connection with the filing of the present Response to our Deposit Account No. 50-4195.

REMARKS

Claims 1-14 are pending in the above-referenced application. Examiner has required Applicant to elect one of groups 1 - 16 in the Office Action under 35 U.S.C.

§121 and 372. Accordingly, Applicant hereby provisionally elects, with traverse, Group I encompassing claims 1-11.

Applicant respectfully points out that Examiners restriction requirements are incorrect for Group 1 – 2 and should be withdrawn for the following reason.

- (i) In Group 1, Examiner states that claim(s) 1-11 drawn to the compound of formula I wherein $Y = S$ and R^5 is H. However, Claim 1 states Y is S, $CR^5=N$ or $N=CR^5$. Therefore, if Y is designated as S in claim 1 then no R^5 group would exist in claim 1.
- (ii) Likewise in Group 2, Examiner states that states that claim(s) 1-11 drawn to the compound of formula I wherein $Y = S$ and R^5 forms a bond with X. However, Claim 1 states Y is S, $CR^5=N$ or $N=CR^5$. Therefore, if Y is designated as S in claim 1 then no R^5 group would exist to form a bond with X in claim 1.

Additionally any groups relying on the Examiner's incorrect restriction requirement in Groups 1 and 2 would need to be withdrawn, including Groups 5, 6, 9, 10, 13 and 14.

I. Traversal

In light of the fact that the issued European Patent 1 658 273 B1, attached hereto, derived its benefits from the same priority document of 60/496,537 08/20/2003, and had the International Application Number of PCT/US2004/024387 08/18/2004 and is commensurate in scope to this Application No.: 10/566,012, Applicant request that the Examiner consider withdrawing the restriction requirement to keep this application in the same scope of EP 1 658 273 B1.

Applicants initially point out that Examiner's requirement for restriction creates 16 separate invention groupings out of only 14 claims. On average, that amounts to 1 claim per invention grouping. In reality, Examiner's requirement is even more burdensome, often requiring multiple restrictions from a single claim. Claim 12, for example, is restricted into 4 separate invention groupings.

In this regard, Applicant respectfully submits that examination of all pending claims 1-14 of the present application is far less burdensome for both Applicant and Examiner than would be prosecution of 16 separately filed applications as a result of Examiner's restriction.

At a minimum, Applicant respectfully requests that Examiner consolidate the numerous groupings sharing the same classification, particularly those sharing both the same class and subclass, such as Groups 1-4. Applicant respectfully submits that such consolidation will impose no serious burden on examination, nor has Examiner alleged that such a burden exists as required under the rules.

A. Groupings.

Examiner's groupings are as follows:

- (1) Groups I-IV classified in class 435, subclass 199;
- (2) Groups V-VIII classified in class 536, subclass 23.2;
- (3) Groups IX-XII classified in class 800, subclass 8;
- (4) Groups XIII-XVI classified in class 435, subclass 19; and

**B. Groupings Sharing The Same Classification
May Be Consolidated In Accordance With The Rules**

The criteria for restriction is set forth in section 803 of the MPEP as follows:

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (A) The inventions must be independent or distinct; and
- (B) There must be a serious burden on the examiner if restriction is required. (emphasis added) (internal citations omitted).

Concerning the second prong, § 803 instructs that examiners establish a “serious burden” by demonstrating one of three prima facie elements:

- (A) the inventions have a separate classification;
- (B) the inventions have a separate status in the art; or,
- (C) the inventions have a different field of search, as defined in MPEP § 808.02.

C. Examiner Does Not Allege That Examination Of Claims Sharing The Same Classification Would Impose A Serious Burden.

- (i) Most claims share a common classification

Though Examiner arguably satisfies the prima facie case with respect to inventions identified as having separate classifications, Examiner passes no judgment on whether examination of inventions sharing the same classification imposes a similar serious burden. Applicant respectfully submits there is none.

Rather, Examiner alleges that the variously defined inventions are “independent” or “distinct” in satisfaction of only the first prong of this two prong test. For example, the identified groupings are described as “unrelated” in paragraph 2, and “distinct” in paragraph 3. However, as § 803 makes clear, independent or distinct inventions must still be examined collectively, i.e., not restricted, unless such examination would impose a serious burden on the examiner.

Groups I-IV, V-VIII, IX-XII and XIII-XVI are each classified in class 435. Accordingly, these groups do not satisfy the first prima facie element for a serious burden set forth under § 803.

- (ii) A separate status in the art is not alleged for groups sharing the same classification

Section 803 makes clear that Examiner may also demonstrate a serious burden where the inventions have acquired a separate status in the art. Examiner makes this allegation in paragraph 9 of the Office Action. However, by Examiner's own admission, this requirement is satisfied only with respect to inventions of different classifications. Paragraph 9 is copied below:

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper. (emphasis added).

Examiner makes no similar allegation of inventions sharing the same classification. Accordingly, Examiner's rejection also fails to satisfy the second prima facie element under § 803.

- (iii) Different Field of Search

The third prima facie element specifies that Examiner may demonstrate that the inventions require a "different field of search." A different field of search is found where it is "necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists" (MPEP § 808.02). However, Examiner makes no allegation that a distinct field of search is required.

Accordingly, Examiner's rejection also fails to satisfy the third and final prima facie element under § 803. None of the three factors of the prima facie case are satisfied with respect to inventions sharing the same classification. It cannot be maintained, therefore, that these inventions impose a serious burden.

**D. Where There Is No Serious Burden
Examination Of The Entire Case “Must” Occur**

Here the MPEP is clear:

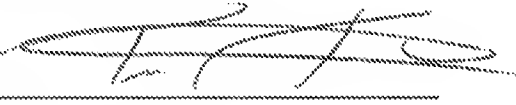
If the search and examination of the entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. (MPEP § 803) (emphasis added).

CONCLUSION

Accordingly, Applicant respectfully requests that Examiner reconsider and withdraw the present restriction requirement, and revise the restriction requirement according to the arguments and suggested groupings presented above.

Dated: February 28, 2008

Respectfully submitted,

By: 

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